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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/508,377	06/09/2000	ZHONGYI LI	054270/0126	7408
22428	7590	06/18/2004	EXAMINER	
FOLEY AND LARDNER SUITE 500 3000 K STREET NW WASHINGTON, DC 20007			BAUM, STUART F	
			ART UNIT	PAPER NUMBER
			1638	

DATE MAILED: 06/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<p align="center">Office Action Summary</p>	Application No. 09/508,377	Applicant(s) LI ET AL.	
	Examiner Stuart F. Baum	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 48-60, 62-65 and 67-69 is/are pending in the application.
- 4a) Of the above claim(s) 55, 57, 58, 63-65 and 67-69 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 48-54, 56, 59, 60 and 62 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 3/10/00, 4/24/03 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>3/31/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

RCE Acknowledgment

1. The request filed on 3/31/2004 for a Request for Continued Examination (RCE) under 37 C.F.R. § 1.114, based on parent Application No. 09/508,377 is acceptable and a RCE has been established. An action on the RCE follows.

The amendment and declaration filed 3/31/2004 have been entered.

Claims 48-60, 62-65, 66-69 are pending.

Claims 61 and 66 have been canceled.

Newly submitted claim 69 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The claim is drawn to a method for suppressing the expression of starch branching enzyme II in a plant using the nucleic acid molecule as specified in claim 48, which is not within the scope of the originally elected group. Applicants elected Group II, drawn to nucleic acid sequences encoding starch branching enzyme II, in the paper filed 7/22/2002.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 69 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Applicant's arguments filed 3/31/2004 have been fully considered but they are not persuasive.

Applicants contend that the present invention was filed under 35 U.S.C. § 371 unity of invention and that unity of invention has to be considered in relation to the independent claims

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(page 9, 4th paragraph). Applicants further contend that “if the independent claims avoid the prior art... no problem of lack of unity arises in respect of any claims that depend on the independent claims. In particular, it does not matter if the dependent claim itself contains a further invention” (sentence bridging pages 9 and 10). Lastly, Applicants contend that claims 55 and 63, and 67-68, and their respective dependent claims, depend from elected independent claims and therefore should be elected under the provisions of PCT Rule 13.1 (page 10, 1st paragraph).

The Office responded to Applicants’ election traversal in the office action dated 10/24/2002, and the response is final. Once the response is final, the proper recourse is for Applicant to file a petition.

Claims 55, 57-58, 63-65, and 67-69 are withdrawn from consideration for being drawn to non-elected inventions.

2. Claims 48-54, 56, 59-60 and 62 are examined in the present office action.

Specification

3. The specification is objected to because the Brief Description of the Drawings does not list all figures properly. Figures 4, 7, 11, and 27 should be listed as “Figure 4A-C”, “Figure 7A-B”, “Figure 11A-C”, and “Figure 27A-R”.

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Information Disclosure Statement

4. The Office acknowledges receipt of Australian Patent No. 730900. Said patent has been placed on form 892 so that said patent will be printed upon issuance of patent for the present application.

Written Description

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 48-50, 52-54, 56, 59-60, 62 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to an isolated nucleic acid molecule that codes for a starch branching enzyme II (SBE II), comprising a nucleotide sequence which hybridizes to SEQ ID NO:10, or wherein the translation product of the nucleotide sequence is 768 amino acids in length, or wherein the nucleotide sequence is functional in wheat, or a sequence encoding a starch branching enzyme II that is derived from a *Triticum* species, or wherein said nucleotide sequence is derived from *Triticum tauschii*, or a method comprising the isolated nucleic acid molecule.

The Applicants isolated their invention from a cDNA library made from wheat endosperm (page 36, line 23) using the maize branching enzyme I as a probe to pull out homologous sequences. A weakly hybridizing clone was isolated and showed greatest homology to maize branching enzyme II. Using this clone (designated SBE-9), the wheat cDNA library was re-screened and four additional clones were isolated which appeared to be separate fragments of the same gene (page 37, line 7). The isolated nucleic acid sequence comprises SEQ ID NO:10 encoding SEQ ID NO:12 (page 37, lines 9-15).

The Applicants do not identify essential regions of SBE II protein encoded by SEQ ID NO:12, nor do Applicants specifically state the hybridization conditions in the claims. The Federal Circuit has recently clarified the application of the written description requirement to inventions in the field of biotechnology. See University of California v. Eli Lilly and Co., 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). In summary, the court stated that a written description of an invention requires a precise definition, one that defines the structural features of the chemical genus that distinguishes it from other chemical structures. A definition by function does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is. The court goes on to say, "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus." *See University of California v. Eli Lilly and Co.*, 119 F.3d 1559; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). Applicants fail to describe a representative number of polynucleotide sequences encoding a SBE II protein falling within the scope of the claimed genus of polynucleotides

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which hybridize to SEQ ID NO:10 and encode a product that is 768 amino acids in length.

Applicants only describe a single sequence of SEQ ID NO:10 encoding SEQ ID NO:12.

Furthermore, Applicants fail to describe structural features common to members of the claimed genus of polynucleotides. Hence, Applicants fail to meet either prong of the two-prong test set forth by *Eli Lilly*. Furthermore, given the lack of description of the necessary elements essential for the SBE II protein, it remains unclear what features identify a SBE II protein. Amending claim 48 to recite the hybridization conditions as specified on page 20, lines 2-5 of the specification and amending the claim to recite that the translation product of 768 amino acids in length has starch branching enzyme II activity will obviate the rejection.

Enablement

6. Claims 48-54, 56, 59-60 and 62 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claimed invention is not supported by an enabling disclosure taking into account the *Wands* factors. *In re Wands*, 858/F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988). *In re Wands* lists a number of factors for determining whether or not undue experimentation would be required by one skilled in the art to make and/or use the invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior

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art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claim.

The claims are drawn to an isolated nucleic acid molecule that codes for a starch branching enzyme II (SBE II), comprising a nucleotide sequence which hybridizes to SEQ ID NO:10, or wherein the translation product of the nucleotide sequence is 768 amino acids in length, or wherein the nucleotide sequence is functional in wheat, or a sequence encoding a starch branching enzyme II that is derived from a *Triticum* species, or wherein said nucleotide sequence is derived from *Triticum tauschii*, or a method comprising the isolated nucleic acid molecule. The Office interprets the claims to read on nucleic acid sequences in sense orientation and the Office interprets the word "altering" in claim 56, line 1, to mean "increasing" the expression of a gene.

The Applicants isolated their invention from a cDNA library made from wheat endosperm (page 36, line 23) using the maize branching enzyme I as a probe to pull out homologous sequences. A weakly hybridizing clone was isolated and showed greatest homology to maize branching enzyme II. Using this clone (designated SBE-9), the wheat cDNA library was re-screened and four additional clones were isolated which appeared to be separate fragments of the same gene (page 37, line 7). The isolated nucleic acid sequence comprises SEQ ID NO:10 encoding SEQ ID NO:12 (page 37, lines 9-15).

Applicants have not reduced to practice their invention. Applicants have not disclosed a plant with an altered (increased) expression of a gene encoding starch branching enzyme II comprising transforming a plant with the nucleic acid molecule according to claim 48. Applicants have also not taught how one skilled in the art would use a plant transformed with the

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nucleic acid molecule of claim 48. The Declaration of Dr. Sadequr Rahman filed 11/3/2003 states "I or others working under my supervision have carried out experiments to down-regulate the expression in hexaploid wheat of the genes corresponding to the SBE II-D1 gene of *T. tauschii* (SEQ ID NO:10),..."(page 3 of the declaration, item 13). Applicants have only indicated that they have down-regulated SBE II activity and have not increased expression of a gene encoding SBE II.

The state-of-the-art teaches that plants transformed with a gene encoding an enzyme involved in starch synthesis does not always produce expected results. Transgenic plants containing ADP-glucose pyrophosphorylase genes behave unpredictably. Sweetlove et al (1996, *Biochem. J.* 320:493-498) found no difference in starch content, tuber number, tuber weight, or metabolite content between potatoes transformed with a gene encoding ADP-glucose pyrophosphorylase and control plants, even though the activity of the enzyme was four-fold higher in the transformed plants (page 495, entire page, and page 497, right column, paragraph 3), but the state-of-the-art teaches isolating DNA fragments using stringent hybridization conditions does not always select for DNA fragments whose contiguous nucleotide sequence is the same or nearly the same as the probe. Fourgoux-Nicol et al (1999, *Plant Molecular Biology* 40 :857-872) teach the isolation of a 674bp fragment using a 497bp probe incorporating stringent hybridization conditions comprising three consecutive 30 minute rinses in 2X, 1X and 0.1X SSC with 0.1% SDS at 65⁰C (page 859, left column, 2nd paragraph). Fourgoux-Nicol et al also teach that the probe and isolated DNA fragment exhibited a number of sequence differences comprising a 99bp insertion and a single nucleotide gap, while the DNA fragment contained 2 single nucleotide gaps and together the fragments contained 27 nucleotide mismatches. Taking

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into account the insertions, gaps and mismatches, the longest stretch of contiguous nucleotides to which the probe could hybridize consisted of 93bp of DNA (page 862, Figure 2). In the present example, the isolated fragment of Fourgoux-Nicol et al exhibits less than 50% sequence identity with the probe to which the fragment hybridized.

In the absence of guidance, undue trial and error experimentation would be required for one of ordinary skill in the art to screen through the multitude of non-exemplified sequences, either by using non-disclosed fragments of SEQ ID NO:10 as probes or by designing primers to undisclosed regions of SEQ ID NO:12 and isolating or amplifying fragments, subcloning the fragments, producing expression vectors and transforming plants therewith, in order to identify those, if any, that when over-expressed have starch branching enzyme II activity and encode a protein of 768 amino acids in length.

Therefore, given the breadth of the claims; the lack of guidance and examples; the unpredictability in the art; and the state-of-the-art as discussed above, undue experimentation would be required to practice the claimed invention, and therefore the invention is not enabled.

Applicant's arguments filed 3/31/2004 have been fully considered but they are not persuasive.

Applicants contend that Dr. Rahman transformed plants with SEQ ID NO:10 in antisense orientation which reduced SBE II enzyme expression and altered starch content (page 13, 1st full paragraph).

The Office contends that the disclosure by Dr. Rahman addresses enablement issues that are not directed to the presently examined invention. Down-regulating SBE II activity using antisense technology is not the subject matter of the currently examined invention. The presently

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elected invention is directed to nucleic acid sequences encoding starch branching enzyme II, which includes nucleic acid sequences in sense orientation only. (See the Requirement for restriction/election, mailed 3/22/2002, and corresponding claims).

7. Claims 48-54, 56, 59-60 and 62 are deemed free of the prior art, given the failure of the prior art to teach or reasonably suggest an isolated polynucleotide of SEQ ID NO:10 encoding SEQ ID NO:12 and a method of increasing the expression of a gene encoding starch branching enzyme II in a plant comprising said polynucleotide.

8. No claims are allowed.

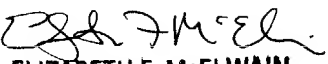
9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stuart F. Baum whose telephone number is 571-272-0792. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 571-272-0804. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Stuart F. Baum Ph.D.
Patent Examiner
Art Unit 1638
June 8, 2004


ELIZABETH F. McELWAIN
PRIMARY EXAMINER
GROUP 1800